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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,423	10/12/2001	Kirk Hogan	HOGAN-06650	2436

23535 7590 05/10/2005

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,423	HOGAN, KIRK	
	Examiner	Art Unit	
	Jeanine A. Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *72-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed February 14, 2005. Currently, claims 72-107 are pending.

2. This action contains new grounds of rejection necessitated by amendment.

3. This action is FINAL.

Priority

4. This application claims priority as a continuation in part of 09/613,887, filed July 11, 2000.

Drawings

5. The drawings are approved by the examiner.

New Grounds of Rejection Necessitated by Amendment

New Matter

6. Claims 72-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" are included. The amendment fails to propose the basis for the new claim. Upon review by the examiner of support for the newly added recitation, the specification does not describe or discuss "a computer program comprising instructions

which direct a processor to analyze data derived from use of said reagents". Instead the specification describes:

> [0186] In some embodiments of the present invention, perioperative genomic profiles are generated using computer-based data analysis of a genetic information sample (e.g., stored nucleic acid sequence information). A sample is collected from a subject at any time (e.g., at birth), sequence information is generated (e.g., through DNA sequencing), and the information is stored (e.g., as digital information on a portable chip). During the perioperative, period, the subject's sequence information is scanned by a computer program for the pre-selected markers. A report (e.g., a perioperative genomic profile) is generated.
>
> [0188] In some embodiments, a computer-based analysis program is used to translate the raw data generated by the genomic profile (e.g., the presence or absence of a given SNP or mutation) into data of predictive value for the clinician (e.g., probability of abnormal pharmacological response, presence of underlying disease, or differential diagnosis of known disease). The clinician (e.g., surgeon or anesthesiologist) can access the predictive data using any suitable means. Thus, in some preferred embodiments, the present invention provides the further benefit that the clinician, who is not likely to be trained in genetics or molecular biology, need not understand the raw data of the genomic profile. The data is presented directly to the clinician in its most useful form. The clinician is then able to immediately utilize the information in order to optimize the perioperative care of the subject.

This description does not support a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. The specification fails to teach a kit comprises each of these components. There is no disclosure in the instant specification of a kit comprising reagents and a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. The instant response does not point to any particular location in the specification for support of this kit and these components.

Moreover, the specification in paragraphs 186 and 188 do not particularly teach even a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. In paragraph 186, there is no description of a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. This paragraph is directed to scanning information of stored information. There is not teachings of any computer program which comprises instructions to direct analysis of data derived from use of said reagents.

With respect to paragraph 188, there is no teachings of a computer program within a kit. Further, there is no teachings of a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents.

The Claims further require instructions which translate data into recommendations for treatment option (claim 75), a display that can be printed (claim 77), instruction direct the fate of said data according to the subject's preference (claim 82). None of these limitations are present in the instant application with regard to a computer program comprising instructions. Claim 84 is directed to a computer program comprising instructions which direct a processor to analyze data to indicate an anesthesia treatment course of action. The specification does not appear to teach any computer program comprising instructions to indicate an anesthesia treatment course of action. There are further no instructions to indicate dosages of compounds (claim 92-94), instructions for prophylaxis for thrombosis (claim 95), for example. The response fails to point to any specific support for these computer programs with these instructions in the response.

The concept of "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" does not appear to be part of the originally filed invention. Therefore, "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 72-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims. See In re Ngai, 367 F.3d

1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Applied Biosystems provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. Applied Biosystems products for sale include: a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. Each of these products is capable of detecting the presence of variant alleles of two or more genes. Applied Biosystems teaches numerous computer programs which are sold with the DNA analysis system, for example. Specifically, DNA analysis system- Model 373 is a system which relies upon gel electrophoresis. Sizing, quantitation and sequencing data are automatically generated by GENESCAN or DNA sequence Analysis software. Applied Biosystems uses fluorescence technology for labeling DNA samples and allows products of all four reactions to be run in the same lane. The color-coded data is graphically represented and a corresponding report gives molecular sizes in base pairs and quantity by relative fluorescence amount (page 136). As seen on page 137, col. 1, DNA sequencing and GENESCAN software generate color-coded data with tremendous explanatory power. A tabular report gives band elution time, base pair size, and relative fluorescence amount. Therefore, the computer program associated with the Applied Biosystems system contains instructions which direct a processor to analyze data derived from the use of the labels, gel,

electrophoretic machine, the power supply etc. The system specifically allows for detection of four labels which would enable detection of variant alleles in two or more genes, associated with two or more conditions, as required by the instant claims.

As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product." Whether the instructions are printed on a piece of paper within the kit or the instructions are printed in the memory of the computer for execution, the instructions remain just instructions. With regard to Claims 73-107, the intended use of the instructions written in the memory or program of the computer would not change the product. As in Ngai, the only difference between the Applied Biosystems system and the instant claims is the content of the instructions. Therefore, the different instructions provided in Claims 73-107 do not distinguish over the prior art.

Therefore, since Applied Biosystems teaches every limitation of the claims, Applied Biosystems anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the specific variant allele elements of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant alleles encompasses any product which may enable detection of variant alleles. The specification, nor the instant claims, limits reagents to be nucleic acid or more

specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the kit containing a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc.meets the limitation of the instant claims.

With response to the arguments directed to instructions, the response traverses the rejection (page 12, of response filed June 3, 2004. The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persuasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains these arguments. Additionally, in view of the recent Federal Circuit case holding that an inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 12-18). Since the facts and analysis of the instant application and Ngai are the same, Ngai is deemed the closest authority on the issue of whether printed instructions in a previously disclosed kit

makes the kit patentable. In the response filed February 14, 2005, the response asserts that Ngai and the instant application are "diametrically distinct." The response asserts that a kit for generating a perioperative genomic profile for a subject is previously undisclosed product and the instructions are interrelated such that instructions of the purpose of generating a perioperative genomic profile do not achieve their purpose of generating a perioperative genomic profile without the reagents and the reagents of the present invention do not product the desired result without instructions. The response concludes by stating "because the instructions of the present invention are 1) functionally related to a 2) previously unknown product, the Applicant is entitled to the claims. This argument has been thoroughly reviewed, but is not found persuasive because the kit is not previously unknown. The kit is merely reagents which are sufficient to detect the presence or absence of variant alleles in two or more genes associated with two or more conditions selected from the group consisting of BchE, CYP2D6, F5, F2, CACNAIS, MTHRF, MTR, MTRR, CBS, TNFalpha, and TNFbeta so as to generate a genomic profile. As stated previously on the record, these reagents encompass nearly any reagents. Labels, electrophoresis gels, sequencing machines, enzymes, for example all are regents for detecting variant alleles. Each of these reagents was previously known and placed in a kit for various purposes. While, the kits taught in the art were not specifically for perioperaive genomic profiling, In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) holds that an inventor could not patent known kits by simply attaching new set of instructions to that product. The instant claims should be no exception to the clearly stated holding of Ngai.

Here the computer comprising instructions for claim 72, for example, which directs a processor to analyze data derived from use of said reagents is literally met by the Applied Biosystems system. With regard to Claims 73-107, the only difference between the claims and the prior art lies in the instructions contained on the computer program.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA. This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process. Further, as argued in the February 14, 2005 response, page 14, the response correctly points out that the only reference to the FDA addresses therapeutic utility. It is clear based upon the silence of the MPEP with regard to the FDA on instructions and kits, that the FDA approval process is not considered in the distinct patenting process.

With respect to the arguments (page 16-17) of the response filed on June 30, 2004 and February 14, 2005, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the

decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

8. No claims allowable over the art.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

J. Goldberg

Jeanine Goldberg
Primary Examiner
May 9, 2005